JAN 10 2013

K122687
510(K) SUMMARY

December 7, 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

CONTACT:
Manfred Abel
Greiner Bio-One North America, Inc.
P.O Box 1026
Monroe, NC 28111

NAME OF DEVICE:

Trade Name:	Blood Culture Holder; Safety Blood Collection Set + Luer Adapter with pre-attached Blood Culture Holder
Common Names/Descriptions:	Tube Holder
Classification Name:	21 CFR 862.1675 Blood specimen collection device
Product Code:	JKA
Class:	II
PREDICATE DEVICE:	Smiths Medical ASD Inc. Saf-T Closed Blood Collection System® (K081229)

DEVICE DESCRIPTION:

INTENDED USE:

Blood Culture Holder:

The Blood Culture Holder is used to fill blood into blood culture bottles and tubes in routine venipuncture procedures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

Safety Blood Collection Set and/or Blood Collection Set + Blood Culture Holder:

The SAFETY Blood Collection Set and/or Blood Collection Set + Blood Culture Holder are used in routine venipuncture procedures. The winged needle of the SAFETY Blood Collection Set is designed with a safety shield, which can be activated to cover the needle immediately

following blood collection to aid in the protection against accidental needlestick injury. The Blood Culture Holder is used to fill blood into blood culture bottles and tubes.

PRODUCT DESCRIPTION:

The Blood Culture Holder is a single-use, non-sterile, plastic holder with threads which are compatible with male luer adapters. The holder can be used with all VACUETTE® Multiple Sample Luer Adapters and Safety Blood Collection Sets for routine venipuncture into various manufacturers' evacuated blood culture bottles and tubes. It is supplied alone or with the Greiner sterile Safety Blood Collection Set with Luer Adapter.

The Blood Culture Holder does not come into contact with the blood specimen. It is an external holder for the Safety Blood Collection Set and the VACUETTE® Multiple Sample Luer Adapter. The Safety Blood Collection Set consists of tubing with a blood collection needle at one end and a female luer at the other. The VACUETTE® Multiple Sample Luer Adapter consists of a male luer at one end and a cannula covered with a sheath. The luer adapter is threaded into the Blood Culture Holder, with the male luer end on the outside and the covered cannula on the inside of the holder barrel. The blood flows through the blood collection needle and tubing of the Safety Blood Collection Set, into the male luer of the VACUETTE® Multiple Sample Luer Adapter, through the luer into the cannula, and into the blood culture tube or holder when punctured by the cannula. The fluid path consists of the Safety Blood Collection Set and the VACUETTE® Multiple Sample Luer Adapter. The Blood Culture Holder never comes into contact with the blood specimen during conditions of use.

When the Blood Culture Holder is supplied attached to the Safety Blood Collection Set and the VACUETTE® Multiple Sample Luer Adapter, it undergoes sterilization as part of the entire system because the fluid path must be sterilized. However, when the Blood Culture Holder is provided alone, it is not sterilized and the user attaches their own sterile blood collection needle and luer adapter.

The Safety Blood Collection Set with Blood Culture Holder is non-pyrogenic and tested according to ISO-10993-11 rabbit pyrogen test. The devices also are below the limit for endotoxin and tested according to ISO-10993-11 LAL Turbidimetric Method.

Caution: US Federal law restricts this device for sale by or on the order of a physician.

SUBSTANTIAL EQUIVALENCE:

The Blood Culture Holder is substantially equivalent to the Smiths Medical ASD Inc. Saf-T Closed Blood Collection System® (K081229) in intended use and design. The similarities and differences are listed below.

	Greiner GBO Blood Culture Holder	**Smiths Medical ASD Inc. Saf-T Closed Blood Collection System® (predicate device)**
510(k) Number	Blood Culture Holder: K122687 Safety Blood Collection Set with Luer Adapter: K011786	K081229
Intended Use	The Blood Culture Holder is used to fill blood into blood culture bottles and tubes in routine venipuncture procedures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.	The Saf-T Closed Blood Collection System® device is intended for use as a direct blood draw device into a vacuum tube or to allow a syringe blood draw and transfer to fill vacuum tubes.
Device Description	Blood culture holder	Blood culture device
Device Design	Cylindrical holder for vacuum bottle and tube placement : cylinder with threads which are compatible with male luer adapters The design of the holder allows collection of blood into blood culture bottles and blood collection tubes.	Cylindrical holder for vacuum bottle and tube placement : cylinder with threads which are compatible with blood collection needles and male luer adapters
Cylinder	Plastic	Plastic

PRODUCT PERFORMANCE:

Simulated blood draw testing was performed on the Safety Blood Collection Set with Luer Adapter and the Blood Culture Holder using a variety of blood culture bottles and evacuated tubes representing the range of bottle and tube sizes. The devices used in the study were:

- Blood collection devices: Greiner Safety Blood Collection Set with Luer Adapter; Blood Culture Holders;
- Blood culture bottles and vials (2 manufacturers);
- Blood collection tubes: VACUETTE® EDTA K2, 4 mL, 13x75mm (smallest diameter cap and tube size) and VACUETTE® Z Serum

Separator and Clot Activator, 7 mL, 16x100mm (largest diameter cap and tube size).

Twenty Blood Culture Holders were connected to 20 Safety Blood Collection Sets with Luer Adapters. The sets were tested in simulated blood draws with blood culture bottles, blood culture vials, and the two tube types.

The results were evaluated for proper fit of the Blood Culture Holders to the Safety Blood Collection Sets, leakage and function of the blood culture containers, and leakage and function of the blood collection tubes. All Blood Culture Holders met the acceptance criteria for fit, leakage, and function when connected to the Safety Blood Collection Sets and when used for blood collection into blood culture bottles and tubes.

Conclusion: The Blood Culture Holder can be used with blood culture bottles, blood culture vials, and the range of blood collection tube sizes from 13x75mm to 16x100mm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2013

Greiner Bio-One North America, Incorporated
C/O Ms. Judith Smith
Principal
Judi Smith, Limited Liability Company
P.O. Box 103
BALDWIN MD 21013

Re: K122687
Trade/Device Name: Blood Culture Holder
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: II
Product Code: JKA
Dated: December 17, 2012
Received: December 20, 2012

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122687

Device Name: Blood Culture Holder

Indication For Use:

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The SAFETY Blood Collection Set and/or Blood Collection Set + Blood Culture Holder are used in routine venipuncture procedures. The winged needle of the SAFETY Blood Collection Set is designed with a safety shield, which can be activated to cover the needle immediately following blood collection to aid in the protection against accidental needlestick injury. The Blood Culture Holder is used to fill blood into blood culture bottles and tubes.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division Sign-Off
Office of Device Evaluation

510(k) K122687